

REMARKS

Claims 34-36 and 48-55, and 59-63 are pending in this application. Claims 46, 47, 56-58, and 64-66 are cancelled without prejudice or disclaimer. Claim 36 is amended in view of the amendment to claim 34. Independent claims 34, 51, and 59 are amended to recite "VERO cells", as explained herein. Applicants limit the independent claims 34, 51, and 59 to Vero cells without prejudice or disclaimer in order to advance the prosecution of this application. However, applicants reserve the right to pursue claims to other cell types in continuation applications. No new matter is introduced. The Office Action is discussed below.

Enablement Rejection:

On pages 2-4 of the Office Action, the examiner maintains the enablement rejection of claims 34-36 and 46-66. The examiner admitted that the specification is enabling for growth of VERO cells in the medium specified in the examples. However, the examiner asserts that the specification does not reasonably provide enablement for a method for producing an immunogenic composition comprising a virus or a virus antigen comprising providing a culture of any cell, or any of a list of the cell types set forth in claims 64-66, 65 and 56-58, grown in any animal protein free medium comprising soy and yeast hydrolysate.

Applicants respectfully disagree with the examiner and reiterate that the specification and examples as disclosed in the specification provide sufficient support and meet the enablement requirement. For example, the specification provides examples of "culture of cells", such as BSC-1 cells, LLC-MK cells, CV-1 cells, COS-cells, VERO cells, MDBK cells, MDCK cells, CRFK cells, RAF cells, RK-cells, TCMK-1 cells, LLC-PK cells, PK15 cells, LLC-RK cells, MDOK cells, BHK-21 cells, CHO cells, NS-1 cells MRC-5 cells, WI-38 cells, BHK cells, and RK-cells. It appears that the examiner expects to see working examples for each cell type that are recited in the claim. Again, applicants disagree and request the examiner to consider the dictates of the MPEP that:

"Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.

An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)).

The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970)."

See MPEP §2164.02 (Rev. 6, September 2007 at 2100-196).

In this case, applicants submit that the specification has set forth representative examples, and that undue experimentation is not required to practice the claimed invention in light of the methods described in the specification and based on what is known in the art.

The examiner also admits that "Shibuya et al. discloses that without the addition of an animal derived product, no growth was observed", that is, the reference teaches away from using animal protein free medium. The examiner states that the reference was cited to show that there is unpredictability involved in cell culture methods, with much experimentation, without predictability, involved in determining a particular cell culture media and method that will allow a cell that is normally present in a living organism, to survive and multiply in artificial cell culture. However, there is unpredictability involved in any procedures if there is a lack of representative example, which is not applicable in this case.

As acknowledged by the examiner and as clarified above, the specification has set forth representative examples, and one skilled in the art would be able to practice

the claimed invention without any undue experimentation in light of the methods described in the specification and based on what is known in the art.

In this context, applicants point out that the common US patent practice allows representative examples while claims recite various cell types that are not shown in the working examples. For example, see US Patent No. 7,115,391 and 6,793,926 disclose representative examples using cell line 293 and claims recite that the cells are selected from CHO, BHK, MDCK, 10T1/2, WEHI cells, COS, BSC 1, BSC 40, BMT 10, VERO, WI38, MRC5, A549, HT1080, 293, B-50, 3T3, NIH3T3, HepG2, Saos-2, Huh7, HER, HEK, HEL, or HeLa cells.

In view of the above, applicants submit that the examiner's rejection is improper. However, in order to expedite the prosecution and for additional clarity, applicants amend the independent claims 34, 51, and 59 to recite "VERO cells", without prejudice or disclaimer. Withdrawal of the alleged enablement rejection is therefore solicited.

Obviousness Rejection:

On pages 4-6 of the office action, the examiner has maintained the obviousness rejection of claims 34-36 and 46-66 over Price *et al.* (WO 98/15614) in view of Kistner *et al.* (US Patent 5,753,489), Luderer *et al.* (US P patent 4,282,315), Gauri *et al.* (US Patent 4,322,404) and Quest International Product Information, Norwich NY, 1995, and Sheffield Pharma Ingredients, Cell Nutrition, Hydrolyzed Proteins & Yeast Extracts, Technical Manual).

Regarding Price *et al.* reference, the examiner speculates, "when one substitutes animal products with soy and yeast cell hydrolysates, one arrives at an animal free culture medium" and such a medium "is not excluded by the reference". Applicants disagree with the examiner and refer to the arguments submitted previously that, the examiner has yet to address the fact that the Price *et al.* reference does not disclose an "animal protein free medium". The Price *et al.* reference does not provide any guidance to a person of ordinary skill in the art to make and use the claimed invention comprising an "animal protein free medium."

Applicants point out that Price *et al.* (WO 98/15614) as published in 1998 did not disclose an animal protein free medium. However, it is the examiner's speculation that such a medium is not excluded from the Price *et al.* disclosure. The examiner also has not considered the fact how one skilled in the art at the time the invention was made would interpret Price *et al.* disclosure in view of Shibuya *et al.* (6,406,909), which was filed July 10, 1998 and issued June 18, 2002. As clarified above, Shibuya teaches away from animal protein free medium, which the examiner also has admitted. Accordingly, at the time the invention was made, one skilled in the art would have no motivation of reconstructing the Price *et al.*'s medium to an animal protein free medium.

The examiner also has not addressed, based on Price *et al.*, how a person of ordinary skill in the art would be able to arrive at the claimed invention without undue experimentation. Consequently, the Price *et al.* reference has not been shown to be enabling.

The examiner refers that "While these rejections may seem contradictory, they are not because each is based upon a different legal analysis, i.e. sufficiency of the disclosure of the instant application to support claims under 35 USC 112, 1st paragraph vs. sufficiency of a prior art disclosure to anticipate or render obvious an embodiment(s) of the claimed invention (See *In re Hafner*, 161 USPQ 783 (CCPA 1969))". However, the examiner has not addressed the issue that Price *et al.* reference has not been shown to be enabling for an animal protein free medium. Thus, there is no basis for the examiner's reliance regarding the sufficiency of Price et al. disclosure to render the claimed invention obvious.

In this context, applicants request the examiner to consider the MPEP that states:

"...rebuttal evidence may include a showing that the prior art fails to disclose or render obvious a method for making the compound, which would preclude a conclusion of obviousness of the compound. A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention." *In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968).

Also, see MPEP §2145 (Eighth Edition, Rev. July 2008).

Applicants also point out that the examiner's position here directly contradicts the enablement rejection, as discussed above. For example, if the practice of the claimed invention comprising growing a culture of cells as recited in claim 47 in an animal protein free medium as recited in claim 34, present a need for "undue experimentation", then the practice of the claimed invention in a medium by reconstructing the Price *et al.*'s medium cannot be obvious to the person of ordinary skill in the art. The examiner also has not addressed this issue.

In view of the above, applicants submit that a *prima facie* case of obviousness has not been established. However, as explained above, in order to expedite the prosecution and for additional clarity, applicants amend the independent claims 34, 51, and 59 to recite "VERO cells", without prejudice or disclaimer. Withdrawal of the alleged obviousness rejection is therefore solicited.

REQUEST

Applicants submit that claims 34-36 and 48-55, and 59-63 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at 202-628-6600 should there be any questions.

Respectfully submitted,



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